

GREENLEE, WINNER and SULLIVAN, P.C.
5370 Manhattan Circle, Suite 201
Boulder, Colorado 80303 USA
Telephone (303) 499-8080
Fax (303) 499-8089

FAX RECEIVED

AUG 19 2003

GROUP 1600

FACSIMILE COVER SHEET

DATE: August 18, 2003

TOTAL NO. PAGES
(incl. cover sheet): 6

TO: Examiner Jon D. Epperson

FIRM NAME: Group 1639, USPTO

FACSIMILE NUMBER: 703-872-9306

FROM: Donna M. Ferber

RE: 10/015,536
Attorney Docket 103-00

OFFICIAL

**IF TRANSMISSION IS UNCLEAR, PLEASE TELEPHONE (303) 499-8080 IMMEDIATELY
AND ASK FOR KAY**

COMMENTS: Petition for Extension of Time and Response to Restriction
Requirement.

CONFIDENTIALITY NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged and confidential. If the reader of this message is not the intended recipient or the agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosing, copying, distributing or the taking of any action in reliance on the contents of this communication is prohibited. If you have received this communication in error, please notify us immediately by telephone (call collect) and return the original to us at the above address via the postal service. Thank you.

#9
YC
8/18/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Kranz et al. : Group Art Unit: 1639

Serial No. 10/015,536 : Examiner: Epperson, Jon D

Filed: December 10, 2001 : Confirmation No. 9971

For: MUTATED CLASS II MAJOR HISTOCOMPATIBILITY
PROTEINS AND COMPLEXES

CERTIFICATE OF TRANSMISSION	
I hereby certify that this correspondence is being transmitted by facsimile to the Patent and Trademark Office No. 703-872-9306.	
18/03/03	<i>John Speaker</i>
Date:	K Speaker

RESPONSE TO REQUIREMENT FOR RESTRICTION

Commissioner of Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed June 3, 2003, Applicants respectfully request reconsideration of the requirement for restriction. This response is accompanied by a Petition for Extension of Time and the necessary fee.

The Requirement for Restriction

The Patent Office has required restriction pursuant to 35 U.S.C. 121 to one of four inventions, which are alleged to be patentably distinct:

- I. Claims 1-10, drawn to a product described as a mutagenized combinatorial library of Major Histocompatibility Complex (MHC) Class II chimeric proteins displayed on the surfaces of recombinant yeast cells, classified variously in class 435, subclass 7.1, DIG 27.

- II. Claims 11-17, drawn to a product described as an isolated mutant MHC class II chimeric protein, classified variously in class 530, subclass 350+; class 424, subclass 192.1.
- III. Claims 18-21, drawn to a method for detection of a lymphocyte having a T cell receptor protein in a biological sample, classified variously in class 435, subclass 4, 7.1
- IV. Claims 22-25, drawn to a method for activating or enhancing an immune response to an abnormal cell, classified variously in class 435, subclass 9.2, FOR 184.

Applicants respectfully elect the claims of Group I for examination with traverse. While the Patent Office has made arguments for the distinctness of the groups, Applicants respectfully submit that the claims of Groups I, II, III, IV, V and VI have, as the heart of the invention, the isolation and characterization of improved MHC Class II chimeric proteins. Accordingly, Applicants respectfully urge that the Examiner rejoin the claims of Groups I, II, III, IV, V and VI for examination because of the relatedness of the subject matter. Applicants make no admission that any one group of claims is obvious over any other group of claims.

SUBGROUP 1: Species of MHC Class II chimeric proteins

The applicants elect, for the purpose of searching, the scl- $\text{A}^{\beta 7}$ construct (SEQ ID NO:17). The portions of this protein are:

1. Linker 1 (residues 7 to 22) (Gly Gly Gly . . . Ser)
2. peptide binding region - $\text{IA}^{\beta 7}$ - β chain (residues 23 to 210) and α chain (residues 220 to 401)
3. Linker 2 - (residues 211 to 219) (Gly Gly Gly . . . Gly)
4. c-myc tag - (residues 402 to 411) (Glu . . . Leu)
5. A detectable label, if present, may be a FITC labeled goat anti-mouse IgG (secondary antibody) with an anti- $\text{IA}^{\beta 7}$ primary antibody.

The amino acid sequence for the scl-A⁹⁷ construct (linker1 - β chain - linker 2 - α chain-c-myc) is given in SEQ ID NO:17, which was submitted with the as-filed application and is found on page 36, lines 31-37.

The signal sequence, peptide and adaptor protein referred to by the Examiner are not contained within SEQ ID NO:17.

SUBGROUP 2: Species of mutation

The applicants elect the mutated protein of GAD65MUT11, whose sequence is given in Figure 8, for the purposes of a search. This figure shows that GAD65MUT11 has mutations in SEQ ID NO:17 at residues 38, 80 and 159 of the β -domain, and residues 30 and 60 of the α -domain.

SUBGROUP 3: Species of autoimmune disease

The applicants elect, for the purposes of a search, the T-cells that target, during an autoimmune response, the insulin producing islet cells of the pancreas (e.g., insulin dependent diabetes mellitus).

CLAIMS WHICH READ ON ELECTED SPECIES:

Claims 1 – 10 read on the elected species.

Conclusion

In view of the foregoing, it is submitted that this case is in condition for allowance, and passage to issuance is respectfully requested.

CONCLUSION

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

This amendment is accompanied by a Petition for Extension of Time (two months) and authorization to charge the amount of \$205 as required under 37 C.F.R. 1.17. It is believed that this response does not necessitate the payment of any additional fees under 37 C.F.R. 1.16-1.17. If the amount submitted is incorrect, however, please charge any deficiency or credit any overpayment to Deposit Account No. 07-1969.

Respectfully submitted,



Donna M. Ferber
Reg. No. 33,878
Customer No. 23713

GREENLEE, WINNER AND SULLIVAN, P.C.

5370 Manhattan Circle, Suite 201
Boulder, CO 80303
Telephone (303) 499-8080
Facsimile: (303) 499-8089
Email: winner@greenwin.com

Attorney docket No.103-00

OFFICIAL